

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

	X	
CITY OF LIVONIA EMPLOYEES'	:	Civil Action No. 1:07-cv-10329-RJS
RETIREMENT SYSTEM, On Behalf of Itself	:	
and All Others Similarly Situated,	:	<u>CLASS ACTION</u>
	:	
Plaintiff,	:	ECF CASE
	:	
vs.	:	PLAINTIFF'S MOTION TO STRIKE AND
	:	MEMORANDUM OF POINTS AND
WYETH, et al.,	:	AUTHORITIES IN SUPPORT THEREOF
	:	
Defendants.	:	
	:	
	X	

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Lead Plaintiff, the Pipefitters Union Local 537 Pension Fund and named plaintiff City of Livonia Employees' Retirement System (collectively, "plaintiffs") hereby move to strike the exhibits attached to the Declaration of Michael J. Chepiga, Esq. (Docket #32) ("Chepiga Decl.") filed in support of defendants' Reply Memorandum of Law in Support of All Defendants' Motion to Dismiss the Consolidated Class Action Complaint (Docket #31) ("Reply"). Plaintiffs hereby move to strike Exhibits 1, 2, 3 and 5 in their entirety, and any reference to them, as they are not referenced in plaintiffs' Consolidated Complaint for Violations of the Federal Securities Laws ("Complaint"), are not matters of public record subject to judicial notice, and cannot be relied upon to contradict the allegations in the Complaint as defendants do here.¹ Plaintiffs also seek to strike any argument based on Exhibit 4 as defendants mischaracterize the contents of the document and also improperly use the document to dispute the Complaint's allegations.

I. INTRODUCTION

In their Reply, defendants improperly rely on the extraneous documents to dispute the Complaint's scienter, falsity and materiality allegations – a strategy which is prohibited at this early stage in the proceedings. Courts in this circuit have long recognized that, when deciding a motion to dismiss, a court may only consider documents attached to the complaint as exhibits, or incorporated in it by reference, and matters of public record subject to judicial notice. *See In re Scottish Re Group Sec. Litig.*, 524 F. Supp. 2d 370, 383 n.99 (S.D.N.Y. 2007) (when considering competing inferences of scienter, the court may only consider "the complaint and other public documents on which Courts ordinarily rely in deciding a motion to dismiss, 'while constantly assuming the plaintiff's allegations to be true'") (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, __ U.S. __, 127 S. Ct. 2499, 2509,

¹ Plaintiffs respectfully request that this motion to strike be heard in conjunction with defendants' motion to dismiss.

2511-12 (2007)); *see also Tellabs*, 127 S. Ct. at 2509 (recognizing the limited exception for consideration of documents that are referenced in or relied upon in the complaint, as well as those that are subject to judicial notice).² These are narrow exceptions and are not intended to grant litigants license to ignore the distinction between motions to dismiss and motions for summary judgment. *Levenstein v. Salafsky*, 164 F.3d 345, 347 (7th Cir. 1998). Moreover, at the motion to dismiss stage extraneous documents certainly may not be considered for the truth of their contents or to dispute plaintiffs' claims. *See In re Omnicom Group, Inc. Sec. Litig.*, No. 02 Civ. 4483 (RCC), 2005 U.S. Dist. LEXIS 5272, at *38-*39 (S.D.N.Y. Mar. 30, 2005) (the court rejected defendants' request for judicial notice of SEC filings to prove the truth of their purported contents). Yet that is exactly what defendants do here.

Disregarding these well established rules defendants improperly rely on Exhibits 1, 2, 3, and 5, none of which are referenced in the Complaint or are matters of public record, to contest the Complaint's well-pled allegations. By doing so, defendants are essentially requesting that the Court disregard plaintiffs' allegations in favor of defendants' version of the facts. Defendants' scheme of essentially skipping to summary judgment while plaintiffs are barred from taking relevant discovery not only violates the clear language of Rule 12(b)(6), it also turns the shield of the Private Securities Litigation Reform Act of 1995's ("PSLRA") stay of discovery into a sword aimed at defeating legitimate claims.

² *See also Rothman v. Gregor*, 220 F.3d 81, 88-89 (2d Cir. 2000) (for purposes of a motion to dismiss, the court's review of documents is limited to documents attached to or incorporated by reference into the complaint, public disclosure documents that have been filed with the SEC and documents upon which plaintiff relied in filing the action); *In re Global Crossing, Ltd. Sec. Litig.*, 313 F. Supp. 2d 189, 195 (S.D.N.Y. 2003) (same).

Accordingly, plaintiffs move to strike the following exhibits and any references made to them in defendants' Reply:

- Exhibit 1: Walter Armstrong, FDA's Approvable Problem, *Pharmaceutical Executive*, Nov. 1, 2007;
- Exhibit 2: John Simons, FDA Damned If It Does, Damned If It Doesn't, *Fortune*, November 9, 2007;
- Exhibit 3: Alicia Mundy, Grassley, Dingell Lead Calls for Overhauling the FDA, *Wall St. J.*, July 30, 2008;
- Exhibit 5: Clinical Study Report for Study 315 dated January 18, 2006 titled "Final Report: A Double-Blind, Randomized, Placebo Controlled Efficacy and Safety Study of DVS SR for the Relief of Vasomotor Symptoms Associated with Menopause."

Plaintiffs additionally seek to strike defendants' improper arguments relating to Exhibit 4, selected pages from Wyeth's presentation at an October 5, 2006 analyst meeting, because they improperly mischaracterize the content of the document and defendants also rely on the contents of the document to dispute the Complaint's allegations of falsity.³

II. ARGUMENT

A. Exhibits 1, 2 and 3 Must Be Stricken as They Are Not Referenced in the Complaint, Are Not Matters of Public Record Subject to Judicial Notice, and Cannot Be Relied Upon to Dispute the Complaint's Scientist Allegations

In their Reply, defendants improperly rely on Exhibits 1, 2, and 3 to challenge plaintiffs' scienter allegations. Exhibits 1, 2 and 3 are articles from *Pharmaceutical Executive*, *Fortune*, and

³ Alternatively, should the Court choose to consider any of the exhibits addressed above, it must convert defendants' motion into one for summary judgment and afford plaintiffs the opportunity to conduct discovery and present evidence in opposition to defendants' motion. See Fed. R. Civ. P. 12(d). Rule 12(d) states, in pertinent part: "If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion *must* be treated as one for summary judgment under Rule 56. All parties *must* be given a reasonable opportunity to present all the material that is pertinent to the motion." *Id.* (emphasis added).

The Wall Street Journal, respectively, which discuss alleged vagaries in the FDA approval process. In fact, Exhibit 2 is simply a vehicle for statements made by defendant Bob Essner regarding his opinions and criticisms of the FDA process. More importantly, all three articles defendants improperly rely on were published *after* the end of the Class Period in this case and thus, are not relevant to any of the issues here.

Defendants attempt to use the articles to purportedly support their factual hypothesis that the FDA process was out of their control and “a tighter approval process than could have been historically anticipated,” thereby somehow negating defendants’ scienter. Reply at 4. Even if this argument was cogent, the Court cannot consider these documents for the purpose of proving or evidencing defendants’ hypotheses.

First, these articles are neither referenced in the Complaint nor matters of public record subject to judicial notice, and therefore it is plainly inappropriate for the Court to give them any consideration. The law is clear on this issue. *See United States SEC v. Power*, 525 F. Supp. 2d 415, 418 n.2 (S.D.N.Y. 2007) (on motion to dismiss the court refused to consider news reports attached to attorney declaration because they were not attached to or referenced in plaintiffs’ complaint); *In re IAC/InterActiveCorp. Sec. Litig.*, 478 F. Supp. 2d 574, 590 n.8 (S.D.N.Y. 2007) (the court did not consider extraneous contracts submitted by defendants in support of their motion to dismiss because the complaint did not rely on the contracts).

Second, while courts have taken judicial notice of articles in determining a motion to dismiss, they have done so for limited purposes, not for the truth of the matter asserted as defendants are improperly asking the Court to do here. *See In re Merrill Lynch & Co. Research Reports Sec. Litig.* 289 F. Supp. 2d 416 (S.D.N.Y. 2003) (the court considered newspaper articles for the limited purpose of showing that investment community was on inquiry notice of defendants’ alleged fraud at

least two years before filing complaint); *In re Alstom SA Sec. Litig.*, 406 F. Supp. 2d 402 (S.D.N.Y. 2005) (court limited its consideration of newspaper articles not referenced in the complaint to the fact of the article's publication and not for the truth of the matter asserted); *In re Take-Two Interactive Sec. Litig.*, 551 F. Supp. 2d 247 (S.D.N.Y. 2008) (court limited the consideration of an analysts' report to the fact of its publication which constituted evidence of how the investing public understood a company disclosure); *Garber v. Legg Mason, Inc.*, 537 F. Supp. 2d 597 (S.D.N.Y. 2008) (plaintiffs alleged that the loss of a key executive should have been disclosed to the public and court allowed defendants' submission of press releases for limited purpose of showing that the information was already publicly reported). While this standard is uniformly acknowledged, defendants disregard it and urge the Court to improperly draw inferences from Exhibits 1, 2 and 3 that their conduct was nonculpable because the FDA was allegedly taking a tougher stance on new drug approvals which they allegedly did not anticipate. Reply at 4 n.3. Defendants' reliance on the documents in this manner is both inappropriate and a mischaracterization of the Complaint's allegations.

Recognizing that plaintiffs' have adequately alleged both falsity and scienter, defendants have resorted to asserting that this case is about nothing more than their failure to get FDA approval and they rely on Exhibits 1, 2, and 3 to support this erroneous interpretation. As pled throughout the Complaint, this case is about defendants' concealment during the Class Period of material adverse data about serious cardiovascular and hepatic adverse effects, including heart attacks, coronary occlusions and hypertension, associated with the use of Pristiq for the treatment of VMS. Complaint, ¶¶67, 78, 84, 90, 95, 105. Regardless of whether the FDA approved Pristiq, defendants failed to disclose known material information about the serious side effects associated with the drug and such a claim is actionable under federal securities law. See *In re Connetics Corp. Sec. Litig.*,

No. C 07- 02940 SI, 2008 U.S. Dist. LEXIS 62515, at *23-*24 (N.D. Cal. Aug. 14, 2008) (court found defendants' statements about the safety of the company's drug Velac were actionable because defendants were aware of studies showing that Velac caused cancerous skin tumors). Thus, defendants' attempt to insert disputed, extraneous facts into their motion to dismiss to contest scienter is improper at this stage of the pleadings and Exhibits 1, 2 and 3 must be stricken. *See Tellabs*, 127 S. Ct. at 2509-10 (on a motion to dismiss the court must accept all factual allegations in the complaint as true and construe them in the light most favorable to the plaintiff: "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one *could draw from the facts alleged.*") (emphasis added).

B. Exhibit 5 Must Be Stricken as It Is Not a Matter of Public Record Subject to Judicial Notice and Cannot Be Relied Upon to Dispute the Complaint's Falsity and Materiality

Similarly, Exhibit 5, a clinical study report for Study 315, must also be stricken as the document is not a matter of public record subject to judicial notice and defendants improperly use the document to challenge the Complaint's falsity allegations. Defendants rely on Exhibit 5 in an effort to contradict the Complaint's allegations that Study 315's adverse events were statistically significant and the use of Pristiq was causally linked to the serious adverse events. Reply at 7 & n.7. These issues are at the heart of plaintiffs' falsity allegations and defendants are simply not permitted to use extraneous documents at this stage to dispute the well pled allegations in the Complaint. *See In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 995 (S.D. Cal. 2005) (defendants' efforts to have court weigh evidence from outside the pleadings is procedurally improper).

Furthermore, Exhibit 5 is not the type of document considered to be a public record. *See In re Astea Int'l Inc. Sec. Litig.*, No. 06-1467, 2007 U.S. Dist. LEXIS 58238, at *24-*25 (E.D. Pa. Aug. 8, 2007) (public records include criminal case depositions, government agency decisions, and published reports of administrative bodies). Exhibit 5 is a clinical study report, prepared by

defendants, and at this stage of the case it is neither relevant nor appropriate for consideration. And, it is certainly improper to accept or consider defendants' self-serving interpretation of the document on a motion to dismiss. *See Immune Response*, 375 F. Supp. 2d at 995 (on a motion to dismiss courts should not generate an evidentiary record and then weigh evidence to dismiss a complaint). By submitting Exhibit 5 defendants ask the Court to impermissibly review facts not in the record and, accordingly, Exhibit 5 and any reference thereto, must be stricken.

C. Defendants Arguments Based on Exhibit 4 Must Be Stricken as They Improperly Mischaracterize the Information and the Document Cannot Be Used to Dispute the Complaint's Allegations

In their Reply defendants, for the first time, assert that they publicly reported the hypertension outcome from the use of Pristiq for VMS during an October 2006 analyst meeting and rely on Exhibit 4 to support their erroneous contention. Reply at 2, 11; Chepiga Decl., Ex. 4. Exhibit 4 consists of a few selected pages of a slide presentation made by defendants at the meeting. Defendants also improperly use Exhibit 4 to attack the Complaint's allegations that the adverse events of hypertension in Study 315 were statistically significant. Reply at 9-10. Both assertions are at best factual interpretations of the proffered document and, in reality, based on a misrepresentation of Exhibit 4 and entirely misleading. Even if the Court were to entertain defendants' efforts to interpret evidence on a motion to dismiss, which it should not, Exhibit 4 does not disclose the results from Study 315, or any other VMS trial, and therefore is not relevant to the allegations here. Rather, Exhibit 4 describes results from studies conducted for Pristiq's use for MDD, which were *not* focused on women suffering from VMS and who would have a heightened sensitivity to hypertension. Thus, any argument based on Exhibit 4 that Study 315's adverse events were not statistically significant is misleading and irrelevant as the information contained therein does not pertain to Pristiq's use for treatment of VMS. Defendants misleading use of Exhibit 4 is improper and any argument based on the Exhibit must be stricken.

III. CONCLUSION

For the reasons set forth above, plaintiffs respectfully request that the Court strike Exhibits 1, 2, 3 and 5 attached to the Chepiga Declaration and any reference thereto in defendants' Reply. Additionally, plaintiffs' request that any argument based on Exhibit 4 be stricken as it mischaracterizes the content of the document and is used by defendants to dispute the Complaint's allegations. In the alternative, should the Court consider any of the exhibits, plaintiffs respectfully request that the Court convert defendants' motion into one for summary judgment.

DATED: September 5, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 5, 2008, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I have mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on September 5, 2008.

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